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09/583,891	05/31/2000	Timothy M. Wiles	39334	4382
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Richard J Rodrick Esq Becton Dickinson and Company 1 Becton Drive			EXAMINER	
			GITOMER, RALPH J	
Franklin Lakes, NJ 07417-1880			ART UNIT	PAPER NUMBER
			1627	7
			DATE MAILED: 09/13/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

Application	No.
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Applicant(s)

09/583,891

Wiles et al.

Examiner

Office Action Summary

Ralph Gitomer

Art Unit **1627**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on May 31, 2000 2a) This action is **FINAL**. 2b) X This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-28 4a) Of the above, claim(s) 11-28 is/are withdrawn from consideration. Claim(s) is/are allowed. 6) X Claim(s) 1-10 is/are rejected. 7) Claim(s) is/are objected to. 8) __ Claims are subject to restriction and/or election requirement. **Application Papers** 9)... The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). All b). Some* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) X Notice of References Cited (PTO-892) Interview Summary (PTO-413) Paper No(s). Notice of Draftsperson's Patent Drawing Review (PTO-948) Notice of Informal Patent Application (PTO-152) Information Disclosure Statement(s) (PTO-1449) Paper No(s). Other

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Applicant's election with traverse of Group I, claims 1-10, in Paper No. 6 s acknowledged. The traversal is on the ground(s) that there is common subject matter in the Groups and two of the Groups are in the same class. This is not found persuasive because the Groups as claimed are distinct inventions requiring different searches in different subclasses.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly

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owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103° and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Clark in view of Wertz.

Clark (6,372,485) entitled *Automated Microbiological Testing Apparatus and Method Therefor teaches in column 2 last full paragraph, an assay for identifying bacteria where six different light frequencies are used sequentially for antimicrobial susceptibility determinations. In column 3 lines 27-30, light of predetermined range of wavelengths is directed toward the wells and detected. In column 4 line 27, the light colors may include red, green, and blue. In column 5 lines 25-30, the detection method measures changes in absorption, scattering and fluorescence as well as luminescence. changes are processed to determine the identification and susceptibility of microorganisms. In column 11 lines 18-32, arrangements for different wavelengths are discussed using UV, red, green, and blue. In column 14 lines 20-25, disclose a value for each well is obtained and sent to a processor. In column 15 first full paragraph, the data is processed and interpreted. column 15 last full paragraph, readings are taken at predetermined intervals. In column 16 lines 15-40, various indicators are shown including redox indicators.

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The claims differ from Clark in that they specify at least two growth indicator values, each representing a respective growth characteristic of said sample, is produced. Also, present claim 3 is directed to turbidity.

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Wertz (4,448,534) entitled *Antibiotic Susceptibility

Testing* teaches in column 4 lines 45-57, optical methods of measurement of the presence of bacteria by nephelometry or turbidity. In column 6 lines 9-18, reading are taken at intervals and stored for processing. In column 7 last three paragraphs, data is stored and processed. In column 8 lines 47-50, algorithms are used. In column 15 line 62 a 96 wells of a tray is shown. In column 16 first full paragraph, microprocessor functions are taught. In column 26 lines 22-33, optical filters are disclosed.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ at least two growth indicator values as shown in Wertz in the method of Clark because Clark teaches multiple readings that are processed and Wertz teaches algorithms are employed to produce various values. Further, turbidity measurements are taught by Wertz where the readings of Clark are directed to color determination. To substitute turbidity measurements for their known function with the color determination of Clark would have been obvious because determination of bacterial concentration in solutions by measuring turbidity is well known in this art.

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Claims 1-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1, the preamble is incomplete and incompatible with the last step in the claim. No function of the method claims is seen. In claim 1 last line, what is respective is not seen.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Clark (6,096,272) teaches microbiological testing.

Fachinger (5,528,363) teaches a polychromator.

Pitner (6,395,506) teaches monitoring cells.

Lancaster (5,501,959) teaches antibiotic susceptibility assays.

Matsumura (6,251,624) teaches assaying microorganisms.

Bochner (6,436,631) teaches antimicrobial analysis, see claim 1.

Pitner (6,395,506) teaches a device for monitoring cells.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (703) 308-4537. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button **Patent Electronic Business Center** for more information.

Ralph Gitomer Primary Examiner Group 1627

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